IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PAR PHARMACEUTICAL, INC., *Plaintiff*, v. PFIZER INC., PFIZER PRODUCTS INC., and C.P. PHARMACEUTICALS INTERNATIONAL C.V., *Defendants*.	Civil Action No. 1:19-cv-00615

COMPLAINT FOR DECLARATORY JUDGMENT
OF PATENT INVALIDITY AND NON-INFRINGEMENT

Plaintiff Par Pharmaceutical, Inc. ("Par") hereby brings this action against Defendants Pfizer Inc., Pfizer Products Inc., and C.P. Pharmaceuticals International C.V. (collectively, "Defendants") seeking a declaration that Par has not infringed, does not infringe, and will not infringe any valid claim of U.S. Patent Nos. 6,890,927 (the "'927 patent") and 7,265,119 (the "'119 patent) (collectively, "patents-in-suit"). Par brings this suit to obtain patent certainty under 21 U.S.C. § 355(j)(5)(C)(i)(I), and to obtain final Food and Drug Administration ("FDA") approval to market its low-cost, generic varenicline tartrate drug product at the earliest possible date pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Par seeks a declaratory judgment of non-infringement and/or invalidity of the patents-in-suit that would allow FDA to approve Par's generic drug application at the earliest possible date, thereby allowing Par to market its low-cost, generic varenicline tartrate drug product.

NATURE AND SUMMARY OF ACTION

1. This action arises under the patent laws of the United States and Amendments to the Federal Food, Drug, and Cosmetics Act (the "Hatch-Waxman Act"),[1] which govern the U.S. FDA approval of both new and generic drugs. *See* 21 U.S.C. § 355 *et seq.*; 35 U.S.C. §§ 156, 217(e). Par seeks FDA approval for the commercial manufacture, use, importation, offer for sale, and sale of a generic version of Chantix (varenicline tartrate) eq 0.5 mg base and eq 1 mg base oral tablets as described in Par's Abbreviated New Drug Application ("ANDA") No. 201785 ("Par's ANDA"). Par's ANDA contains a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '927 and '119 patents are invalid or will not be infringed by the manufacture, use, or sale of the Par's varenicline tartrate product ("Par's ANDA Product").

2. The '927 and '119 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Chantix.

3. In accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Actavis Pharma Manufacturing Pvt. Ltd., Par's predecessor in interest with respect to Par's ANDA, sent notice on February 15, 2011 to Pfizer Inc., CP Pharmaceuticals International C.V., and Pfizer Products Inc. of patent certifications for the '927 and '119 patents and provided an Offer of Confidential Access and Confidentiality Agreement ("OCA") to Par's ANDA.

4. The Hatch-Waxman Act provides for a "civil action to obtain patent certainty" when a generic applicant makes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc). This declaratory judgment provision in the Hatch-Waxman Act aims to encourage early resolution of patent disputes, and prevent brand-name drug

[1] Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355(j) (1984).

companies from using tactics that forestall the competing generic drug makers from entering the market. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008).

5. Par's complaint seeks a judgment to obtain patent certainty that Par's ANDA Product does not infringe any valid and enforceable claim of the '927 and '119 patents. Such judgment would enable Par to bring Par's ANDA Product to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions.

THE PARTIES

6. Par is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Rd., Chestnut Ridge, NY 10977.

7. On information and belief, Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. According to the United States Patent and Trademark Office ("USPTO") Assignment database, Pfizer Inc. is an assignee of the '927 and '119 patents as of January 17, 2019. On information and belief, Pfizer Inc. is the holder of New Drug Application ("NDA") No. 021928 for Chantix (varenicline tartrate) eq 0.5 mg base and eq 1 mg base oral tablets.

8. On information and belief, Pfizer Products Inc. is a corporation organized and existing under the laws of the State of Connecticut, having a place of business at Eastern Point Road, Groton, CT 06340. Pfizer Inc. is the ultimate parent of Pfizer Products Inc. According to the United States Patent and Trademark Office ("USPTO") Assignment database, Pfizer Products Inc. is an assignee of the '927 patent as of January 17, 2019.

9. On information and belief, C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having

a place of business at 235 East 42nd Street, New York, New York 10017. On information and belief, Pfizer Inc. is the ultimate parent of C.P. Pharmaceuticals International C.V. and has exclusively licensed the '927 and '119 patents to C.P. Pharmaceuticals International C.V.

JURISDICTION AND VENUE

10. This is a Complaint for declaratory judgment that the claims of the '927 and '119 patents are invalid and that Par has not, does not, and will not infringe the claims of the '927 and '119 patents, which arise under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, the Hatch-Waxman Act, 21 U.S.C. §§ 355(j) *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq.*), the Declaratory Judgment Act (28 U.S.C. §§ 2201-02), 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

12. This Court has personal jurisdiction over Defendants at least because of their continuous and systematic contacts with the state of New York, including conducting of substantial and regular business therein through marketing and sales of pharmaceutical products in New York including, but not limited to, the Chantix product.

13. This Court has personal jurisdiction over Defendants at least because Defendants, upon information and belief, (1) directly or indirectly market and sell pharmaceutical products throughout the United States and in this judicial district and (2) have consented to personal jurisdiction in this judicial district by filing of suits in this judicial district, including, but not limited to *Pfizer Inc. v. Mylan Inc.*, 1:10-cv-06463-WHP; *Pfizer Inc. v. Apotex Inc.*, 1:10-cv-06464-WHP; and *Pfizer Inc., v. Intellipharmaceutics Int'l Inc.*, 1:14-cv-06373-GHW, thereby having availed themselves of the rights and benefits of New York law. Upon information and

belief, Defendants purposefully have conducted and continue to conduct business in this judicial district, and this judicial district is a destination of Defendants' pharmaceutical products.

14. Venue is proper in this District under 28 U.S.C. §§ 1391, 1400, and/or 21 U.S.C. § 355.

HATCH-WAXMAN OVERVIEW

15. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e). The Hatch-Waxman Act was intended to encourage generic-drug competition while leaving intact incentives for research and development of new drugs by pioneering, i.e., "branded," drug companies. *See* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648. To accomplish this goal, the Hatch-Waxman Act established a framework with certain elements that are pertinent here.

16. First, a company seeking FDA approval of a new drug must submit an NDA to FDA. *See* 21 U.S.C. § 355. A brand-name drug sponsor must also inform FDA of every patent that claims the "drug" or "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *See* 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(b), (c)(2). Upon approval of the NDA, FDA publishes a listing of patent information for the approved drug in a document referred to as the Orange Book. *See* 21 U.S.C. § 355(b)(1). The new FDA-approved drug is known as the "reference-listed drug."

17. Second, the Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug manufacturer must submit an ANDA to FDA. An ANDA is "abbreviated" because applicants are generally not required to include the extensive pre-clinical and clinical data that must be

included in an NDA for a brand-name drug. Instead, the ANDA applicants can rely on the NDA's pre-clinical and clinical data if the proposed generic product is "bioequivalent" to the corresponding reference-listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

18. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market its generic product; or (iv) that the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a "paragraph IV certification."

19. An applicant submitting an ANDA containing a paragraph IV certification must provide formal written notice (i.e., "a notice letter") informing both the patent holder and the NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

20. Third, the Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if a paragraph IV certification has been made. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent owner brings suit within 45-days of receiving notice of the paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of approval by FDA of the ANDA to allow parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

21. Fourth, the Hatch-Waxman Act allows ANDA applicants to bring declaratory judgment actions against an NDA holder or an owner of an Orange-Book-listed patent if (1) neither the patent owner nor the NDA holder brought an action for infringement of the patent

within the 45-day period; and (2) the ANDA applicant's notice of paragraph IV certification included an offer of confidential access to the ANDA. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

ACTIONS GIVING RISE TO THIS SUIT

22. Actavis Pharma Manufacturing Pvt. Ltd., Par's predecessor in interest with respect to Par's ANDA, submitted Par's ANDA to FDA seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of a generic version of Chantix (varenicline tartrate) eq 0.5 mg base and eq 1 mg base oral tablets. Pursuant to an Asset Purchase Agreement dated September 24, 2012, Par acquired ownership and all rights to Par's ANDA. Par's ANDA contains a paragraph IV certification that the '927 and '119 patents are invalid and/or will not be infringed by the manufacture, use, or sale of Par's ANDA Product.

23. On February 15, 2011, pursuant to 21 U.S.C. § 355(j)(2)(B)(i), Actavis Pharma Manufacturing Pvt. Ltd., Par's predecessor in interest with respect to Par's ANDA, sent notice to Pfizer Inc., CP Pharmaceuticals International C.V., and Pfizer Products Inc. of patent certifications for the '927 and '119 patents and provided an OCA to Par's ANDA.

24. Neither the patent owner of the '927 and '119 patents nor the NDA holder for Chantix brought an action for infringement of the patents within the 45-day period.

25. Accordingly, both requirements are met for the declaratory judgment action expressly authorized by the Hatch-Waxman Act: (1) the 45-day period has passed without any of Pfizer Inc., CP Pharmaceuticals International C.V., or Pfizer Products Inc. bringing an action for infringement, and (2) Actavis Pharma Manufacturing Pvt. Ltd., Par's predecessor in interest with respect to Par's ANDA, made the statutory offer of confidential access in connection with the '927 and '119 patents. 21 U.S.C. § 355(j)(5)(C)(i).

26. This provides Par with a statutory right to bring the present declaratory judgment action for patent certainty. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

27. Defendants have demonstrated their intent to enforce Orange Book-listed patents for Chantix and have filed suit against other parties alleging infringement of the '927 and '119 patents. *See Pfizer Inc. v. Mylan Inc.*, 1:10-cv-06463-WHP (S.D.N.Y.); *Pfizer Inc. v. Apotex Inc.*, 1:10-cv-06464-WHP (S.D.N.Y.).

28. Par requested, but Defendants did not provide, a covenant not to sue Par on the '927 and '119 patents.

29. Defendants' actions have resulted in a substantial controversy regarding the '927 and '119 patents between Par and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that the '927 and '119 patents are not infringed and/or invalid.

PATENTS-IN-SUIT

30. On its face the '927 patent entitled "Tartrate Salts of 5,8, 14-Triazateracyclo[10.3.1.02,11 04.9]-Hexadeca-2(11), 3,5,7,9-Pentaene And Pharmaceutical Compositions Thereof" indicates it was issued by the USPTO on May 10, 2005. A copy of the '927 patent is attached as Exhibit A.

31. According to the records at the USPTO, Pfizer Inc. and Pfizer Products Inc. are the assignees of the '927 patent.

32. On its face the '119 patent entitled "Tartrate Salts of 5,8,14-Triazateracyclo[10.3.1.$0^{2,11}$.$0^{4,9}$]-Hexadeca-2(11), 3,5,7,9-Pentaene And Pharmaceutical Compositions Thereof" indicates it was issued by the USPTO on September 4, 2007. A copy of the '119 patent is attached as Exhibit B.

33. According to the records at the USPTO, Pfizer Inc. is the assignee of the '119 patent.

COUNT ONE

Declaratory Judgment Regarding Non-Infringement of U.S. Patent Nos. 6,890,927 and 7,265,119

34. Par realleges paragraphs 1 to 33 above as if fully set forth herein.

35. There is an actual, substantial, and continuing justiciable case or controversy between Par and Defendants regarding the infringement of the '927 and '119 patents.

36. Par's submission of Par's ANDA has not infringed any claims of the '927 and '119 patents, either literally or under the doctrine of equivalents.

37. Par's manufacture, marketing, use, offer for sale, sale, and/or importation of Par's ANDA Product will not directly infringe or induce or contribute to the infringement by others of any claims of the '927 and '119 patents, either literally or under the doctrine of equivalents.

38. Par is entitled to a declaratory judgment that Par does not infringe the claims of the '927 and '119 patents.

COUNT TWO

Declaratory Judgment Regarding Invalidity of U.S. Patent Nos. 6,890,927 and 7,265,119

39. Par realleges paragraphs 1 to 38 above as if fully set forth herein.

40. There is an actual, substantial, and continuing justiciable case or controversy between Par and Defendants regarding the invalidity of the '927 and '119 patents.

41. The claims of the '927 and '119 patents are invalid at least for the failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

42. Par is entitled to a declaratory judgment that the claims of the '927 and '119 patents are invalid.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests this Court enter judgment as follows:

A. Declaring that Par's submission of Par's ANDA has not infringed any claims of the '927 and '119 patents, either literally or under the doctrine of equivalents.

B. Declaring that Par's manufacture, marketing, use, offer for sale, sale, and/or importation of Par's ANDA Product will not infringe or induce or contribute to the infringement by others of any claims of the '927 and '119 patents, either literally or under the doctrine of equivalents;

C. Declaring that the claims of the '927 and '119 patents are invalid; and

D. Awarding Par such other relief that the Court deems just and proper.

Dated: January 22, 2019

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